

REMARKS

Claims 1-20 are pending. Claims 5, 8-12, and 15-20 have been withdrawn from consideration.

Claims 1, 3-4, 6, and 13-14 have been rejected as allegedly anticipated under 35 U.S.C. § 102(b) over U.S. Patent No. 6,455,053 to Okada et al. (“*Okada*”). Claim 1-4, 6-7, and 13-14 have been rejected as allegedly obvious under 35 U.S.C. § 103 over *Okada*. Claim 6 have been rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Claims 1 and 4 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

By this Amendment, Applicants amended claims 1 and 4, and added new claim 21. Applicants respectfully request reconsideration and allowance of all pending claims in view of the remarks set forth below.

I. ANTICIPATION REJECTION OVER *OKADA*

The Examiner has rejected claims that recite a drop pill comprising a pharmaceutical active and a matrix adjuvant over *Okada*. *Okada* describes pharmaceutical product formulations, which are clearly not “drop pills,” prepared by mixing the ingredients to form a suspension, charging the suspension through a hole, and air-drying the resulting composition (*Okada*, e.g., Examples 9 and 12). The Examiner stated that “[a] preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness.” *See* Office Action, at p. 4. On this basis, the Examiner refused to consider the preamble limitation “a drop pill” limiting, and rejected the claims as anticipated by *Okada*.

Applicants respectfully disagree.

The Examiners are explicitly instructed to consider the entire claim, including the preamble during examination:

The entire claim must be considered, including the preamble language; and the transitional phrase. The claim as a whole, including all limitations found in the preamble; the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement.

*Written Description Guidelines*, 66 Fed. Reg. 1105 (2001). *See also* MPEP §2161. The preamble

is limiting when it is “essential to point out the invention defined by the claim.” MPEP §2111.02; *Kropa v. Robie*, 88 U.S.P.Q. 478 (C.C.P.A. 1951). The entirety of the patent application must be considered to determine whether the preamble is necessary to give “life, meaning and vitality” to the claim. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 9 U.S.P.Q.2d 1962, 1966 (Fed. Cir. 1989). The Examiner is respectfully directed to MPEP §2111.02, which discusses *Kropa* and *Corning Glass*. When a preamble recites a structural feature of the invention, the preamble is limiting. MPEP §2111.02, *citing*, *Corning Glass*, 9 U.S.P.Q.2d at 1966. In *Kropa*, the preamble recited an “abrasive article.” The court stated that “it is only by that phrase [preamble] that it can be known that the subject matter defined by the claims is comprises as abrasive article [language in brackets added].” MPEP §2111.02, *citing*, *Kropa*, 88 U.S.P.Q. at 481.

The preamble of amended claim 1 recites a “drop pill.” There can be little doubt that “drop pill” is structure. Further, there is also little doubt that the term “drop pill” has meaning only when the specification is considered. The meaning to the term “drop pill” is given throughout the specification. It refers to a pharmaceutical product formulation prepared by dripping a solution, suspension, or emulsion of the drug and the adjuvant into a coolant. *See, e.g.*, Background and throughout the Examples. Without the recitation of “drop pill” in the preamble, the claims would cover any pharmaceutical formulation containing any active ingredient and a variety of excipients. Such overly broad reading of the claims would be clearly contrary to the specification and the intent of the Applicants. Therefore, the preamble of claim 1 give life and meaning to the claims and as such it is limiting.

A finding of anticipation requires disclosure of each and every claim limitation in a single prior art reference, either explicitly or inherently. MPEP §2131; *In re Omeprazole Patent Litigation*, 483 F.3d 1364, 1371 (Fed. Cir. 2007). The analysis involves a comparison between the construed claim and the prior art reference. *Id.* *Okada* does not disclose “drop pills.” It appears the Examiner’s reference to the preamble recognizes absence of anticipation if the preamble is limiting. The specification of the present application defines a “drop pill” as a pharmaceutical product formulation prepared by dripping a solution, suspension, or emulsion of the drug and the adjuvant into a coolant. *Okada*’s formulations are prepared by a completely different methodology.

Withdrawal of the anticipation rejection over *Okada* is respectfully requested.

## II. OBVIOUSNESS REJECTION OVER OKADA

The Examiner has rejected claims 1-4, 6-7, and 13-14 as allegedly obvious over *Okada*. The Examiner's reasoning appears to be based on assuming the preamble of claim 1 is not limiting.

Applicants respectfully disagree and reference the previous section herein above.

First, to establish a *prima facie* case of obviousness, the Examiner must show that the prior art discloses, teaches or suggest each limitation of the claims at issue, MPEP §2143.03, or at least provides an "apparent reason" to modify the prior art in the direction of the claimed invention. *KSR Int'l v. Teleflex, Inc.* 127 S. Ct. 1727, 1741 (2007). Nothing in *Okada* discloses, teaches, or suggests the "drop pill" of claim 1. Further, nothing in *Okada* provides an "apparent reason" to modify the air-dried formulation product of *Okada* in the direction of the drop pills claimed in the present patent application.

Second, to establish a *prima facie* case of obviousness, the Examiner must show that one skilled in the art would have a reasonable expectation of success to modify *Okada* in the direction of the drop pill" of claim 1. MPEP §2143.02. Since the preamble is limiting, the Examiner is respectfully requested to point out why one skilled in the art would have such an expectation based on the disclosure of *Okada*.

Withdrawal of the obviousness rejection over *Okada* is respectfully requested.

## III. WRITTEN DESCRIPTION REJECTION

Claim 6 have been rejected for alleged failure to comply with the written description requirement. In particular, the Examiner objected to the recitation of derivatives of starch and cellulose.

Applicants respectfully disagree.

The standard for compliance with the written description requirement is well established. MPEP §2163. The description as filed is presumed to be adequate. MPEP §2163.04. There is a strong presumption that original claims are supported in the application as filed. MPEP

§2163.I.A. Whether or not the meaning of “derivatives of starch” is clear to an artisan, the original claim supports itself from the written description standpoint and legal basis can be reasonably raised in this regard from the standpoint of 35 U.S.C. §112, first paragraph.

Furthermore, any person skilled in the art can understand that the “derivatives of starch or cellulose” refers to the functional equivalents of starch or cellulose. Although the specification does not describe the chemical structure of said derivatives of starch or cellulose, such definition is not legally required and one skilled in the art would understand the meaning of this term from the prior art as a whole. Withdrawal of this rejection is respectfully requested.

#### IV. INDEFINITENESS REJECTIONS

Claims 1 has been rejected as indefinite for lack of antecedent basis. Applicants amended Claim 1 to address the rejection. The amendment obviated the rejection.

Claim 4 has been rejected as allegedly indefinite for reciting ‘crystal water.’ Claim 4 has been amended, with the objectionable recitation being deleted. The amendment obviated the rejection. New dependent claim 21 was added to cover the same subject matter.

The applicants therefore respectfully request reconsideration and allowance in view of the above remarks and amendments. The Examiner is authorized to deduct additional fees believed due from our Deposit Account No. 50-4711.

Respectfully submitted,

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